(12) UK Patent Application (19) GB (11) 2 121 289 A

(21) Application No 8311183
(22) Date of filing 25 Apr 1983
(30) Priority data
(31) 3204/82
(32) 4 May 1982
(33) Czechoslovakia (CS)
(43) Application published
21 Dec 1983
(51) INT CL³
A61F 5/47
(52) Domestic classification
A5R EU
(56) Documents cited
GB 1334613
GB 1318175
(58) Field of search
A5R
(71) Applicant
Chirana Vyzkumny ustav zdravotnicke techniky koncernova ucelova organizace (Czechoslovakia),
3 Kamenice, Brno,
Czechoslovakia
(72) Inventors
Valter Jakubek,
Jiri Sracek,
Karel Stolpa
(74) Agent and/or Address for Service
Saunders and Dolleymore,
2 Norfolk Road,
Rickmansworth, Herts.
WD3 1JH

(54) **Intrauterine contraceptive device and method of its production**

(57) Intrauterine contraceptive devices made of synthetic polymer combined with metal include 1 to 30% wt. of at least one metal ingredient in a powdered state selected from copper, silver, gold and zinc. The powdered metal is distributed throughout the polymer material homogenously, and has a particle size of from 2 to 50 μm.

GB 2 121 289 A

SPECIFICATION

Intrauterine contraceptive device and method of its production

The invention relates to intrauterine contraceptive devices made of synthetic polymer combined with metal, the synthetic polymer containing a metal ingredient.

At the present time there are approximately 80 million women all over the world using intrauterine contraceptive devices, including about 400,000 women in Czechoslovakia. The significance of family planning in the life of modern man is rising. The concept of "family planning" has both quantitative and qualitative aspects, namely to ensure the birth of physically and psychologically sound children and to help individuals with reduced fertility or infertility to obtain desired fertility. Contraception seems to be the most convenient method for family planning. Contraception comprises means that enable the sexual intercourse of two fertile heterosexual individuals without the conception of a new individual, these methods being reversible. Neither abortion (being a repressive method), nor sterilization, nor sexual abstinence are included. High demands are made on contraception. The method is required to be reliable, safe, and innocuous to health, and at the same time aesthetically acceptable and comparatively cheap. No means meeting all these demands has yet been developed in the world. In the early 1960's the first generation of intrauterine contraceptive devices (IUCD) made of synthetic polymer without metal were developed. They suffered from a relatively large number of failures and secondary unfavourable effects comprising spontaneous IUCD expulsion from the uterine cavity, bleeding and/or pain in consequence of which it was necessary to remove the IUCD from the uterus.

These disadvantages and experience led to the development of intrauterine contraceptive devices of the second generation that keeps both accordion effect (returns to its original shape) and the principle of uterine fundus search (returns to its original position). It is important that the shape and the size of intrauterine contraceptive devices approach the size and the shape of the uterine cavity into which the IUCD shall be inserted as optimally as possible. The intrauterine contraceptive device should be made of such material and be of such shape so as to have sufficient resilience to adjust to changes in the shape of the uterine cavity during the menstruous cycle and during uterine contractions. It should have sufficient plastic shape memory to return to its original shape and original position after the removal of these influences when the IUCD is to occupy the uterine fundus with its largest part. In spite of improved results the intrauterine contraceptive devices of the second generation were not of 100% reliability and without secondary effects such as expulsion, bleeding, and pain. This was the reason for the development of intrauterine contraceptive devices of the third generation. "Medicate IUCD" was made by adding an effective substance. A metal is used as the effective substance most often, the metal being copper in the form of wire or a thin tube slid on or would round a part of intrauterine contraceptive device or in its surface layer. The disadvantage of metal used in the form of wire or a tube lies in metal corrosion in the intrauterine medium with subsequent wire or tube breakage, which increases the injury hazard. Higher consumption of labour during IUCD production is not negligible either.

Synthetic steroids released from the intrauterine contraceptive device from a reservoir into the intrauterine medium are often used too. The service life of intrauterine contraceptive devices with a reservoir of synthetic steroid hormones is restricted — as far as the release of this substance is concerned — because the reservoir empties within one or two years. Then it is necessary to withdraw the IUCD and substitute a new one. Another disadvantage of the intrauterine contraceptive device is that to reveal it (e.g. by X-rays) in the uterine cavity it is necessary to add a contrastive substance (for example barium sulphate) up to 25% by weight to the IUCD material, which reduces the possibility of increasing the metal content in the IUCD material.

The drawbacks mentioned above do not concern intrauterine contraceptive devices made of a synthetic polymer combined with metal according to the following invention.

The IUCD material includes at least one metal ingredient in a powdered state from 1 to 30% by weight selected from group Ib of the 4th, 5th or 6th periods or from group IIb of the 4th period of the periodic table. The powdered metal is distributed throughout the material homogeneously, the size of the particles being from 2 to 50 μm.

The material of the IUCD may contain copper in a quantity up to 25% by weight with silver added in a quantity up to 5% by weight.

The material of the IUCD may contain zinc in a quantity up to 25% by weight with silver added in a quantity up to 5% by weight.

A method of producing an intrauterine contraceptive device in accordance with the present invention is as follows:—

Synthetic polymer and powdered metal ingredient are homogenized in a mixing device and then remelted in a homogenizing extruder. The extrudate is granulated, then the granulated synthetic polymer with metal content is converted to a thermoplastic state in the fusion chamber of an injection press and then injected into the mould from which it is taken out as a finished intrauterine contraceptive device.

The advantage of an IUCD made of synthetic polymer with a metal content in accordance with the present invention lies in excluding undesirable effects with almost 100% effectiveness because the synthetic polymer is directly filled with a powdered metal up to 30% by weight. The powdered metal is released in a regulated quantity

owing to the complex function of the uterus. Thus the long-term effectiveness of the intrauterine contraceptive device is ensured without injury hazard because metal is distributed throughout the IUCD material. Substitution of a contrastive substance (for example barium sulphate) for metal enables the detection of the IUCD placed in the uterine cavity by means other than X-ray methods. Higher content of metal results in a greater likelihood of the IUCD retaining its resilience, which is important for its complex function. Reduced consumption of labour during its production seems to be another advantage. Reducing the number of abortions and health damage after abortion and saving bed capacity by securing as many women as possible for suitable contraception, is not negligible either. If one third of undesirable conceptions of 1,500 women resulting in abortions is avoided, 1,000 — 1,500 bed/days are saved. This capacity can then be devoted to care for risk pregnancies or to the intensification of care for women suffering from gynaecological diseases.

Non-limiting examples of methods of IUCD production according to the present invention are as follows:

An IUCD made of a synthetic polymer combined with metal is formed by a synthetic polymer which contains a powdered metal ingredient from 1 to 30% by weight, the powdered metal being either copper, or zinc, or silver, or gold, and/or a mixture thereof (the preferred mixture being of copper and silver, or zinc and silver). The maximum metal weight ratio depends on the excreted metal volume limited by the quiescent physiological value of metal excreted in the urine (for copper 0.75 ± 0.25 μmol/24 hours, for zinc 2.76 ± 0.38 μmol/24 hours, for silver 5.88 ± 0.56 μmol/24 hours).

The contaceptive effect of the IUCD according to this invention is complex and caused by the stimulation of the natural defensive capabilities of the human body. The IUCD inserted into the uterine cavity causes the emergence of an enormous number of macrophages that attack the foreign body placed in the intrauterine cavity. Thus the immune response of the body is evoked because excited macrophages attack both the IUCD placed in the uterine cavity and spermatozoa moving into the intrauterine cavity. On the immunity side, spermatozoa are foreign to the woman's body, therefore they are phagocytosed by macrophages. Thus the number of spermatozoa is radically reduced and conception becomes impossible. Normally fertile semen (normospermia) becomes less fertile (oligospermia) and then infertile (azoospermia). These facts are important in understanding the contraceptive effect for what is meant is a real contraceptive effect and not an antiembeddive or abortive effect. The contraceptive effect of the IUCD is increased by adding a metal because a higher number of macrophages are excited so that smaller IUCD's can be used. Thus unfavourable bleeding effects and/or pain are reduced.

Experiments carried out by means of a scanning electron microscope have proved the macrophage phagocytizing effect. By adding one or more powdered metals to the polymer material it is possible to achieve the uniform distribution of metal and its release throughout the uterine cavity. In this it differs from an IUCD with wire or a thin tube wound round it, when release is not ensured from the whole surface of the intrauterine contraceptive device.

The following processes take place during the long-term insertion of the IUCD with metal within the uterine cavity:

(a) metal gets to the surface of a polymer material,

(b) metal diffuses from the interior of the device to its surface,

(c) the speed of metal release from the polymer material is influenced by the swelling of the IUCD, by the increase of porosity, and thus by the speed of diffusion processes of metal to the surface and from the surface into the surrounding medium,

(d) silver present in the material of the IUCD operates bactericidally.

A method of producing an IUCD made of synethetic polymer combined with metal can be practised as follows.

A weighed volume of basic synthetic polymer and required ingredient are homogenized in a suitable mixing device, then remelted in an extruder with high homogenizing effectiveness. The polymer extrudate is granulated by means of a granulating cutting machine, then the granulated synthetic polymer with metal content is converted into a thermoplastic state in the fusion chamber of an injection press. Then it is injected into a mould from which it is taken out as a finished intrauterine contraceptive device. The advantages of this method lie in the possibility of exact addition of powdered metals to powdered synthetic polymer (the preferred being copolymeric ethyl vinyl acetate) and its homogenization by means of a double-screw extruder.

An IUCD in accordance with the present invention can be used in veterinary practice too.

CLAIMS

1. An IUCD made of a synthetic polymer combined with metal containing at least one metal ingredient in a powdered state from 1 to 30% by weight selected from group Ib of the 4th, 5th, or 6th periods or from group IIb of the 4th period of the periodic table, the powdered metal being distributed throughout the material of the IUCD homogenously and having a particle size of from 2 to 50 μm.

2. An IUCD according to Claim 1 containing copper in a quantity up to 25% by weight with silver added to it in a quantity up to 5% by weight.

3. An IUCD according to Claim 1 containing zinc in a quantity up to 25% by weight with silver added to it in a quantity up to 5% by weight.

4. A method of producing an intrauterine contraceptive device in which a synthetic polymer

and powdered metal ingredient are homogenized in a mixing device, remelted in a homogenizing extruder, extruded, granulated, and the granulated synthetic polymer with metal content converted into a thermoplastic state in the fusion chamber of an injection press and injected into a mould from which it is taken out as a finished intrauterine contraceptive device.

5. An IUCD made of a synthetic polymer combined with metal substantially as hereinbefore described with reference to the Examples of the invention.

6. A method of producing an intrauterine contraceptive device substantially as hereinbefore described with reference to the Examples of the invention.

Printed for Her Majesty's Stationery Office by the Courier Press, Leamington Spa, 1983. Published by the Patent Office 25 Southampton Buildings, London, WC2A 1AY, from which copies may be obtained.